NeoTest

An AMC for a neonatal sepsis diagnostic

Neonatal sepsis is a major contributor to infant death and disability worldwide - it causes 400,000–700,000 deaths per year, mostly in low and middle income countries. Rapid diagnostic tests could significantly reduce mortality and AMR. Our preliminary analysis shows that a diagnostic would save an additional year of healthy life for $15, and reduce unnecessary antibiotic use in neonates by 60%. Despite this, no diagnostic currently exists, reflecting market failures which undermine the commercial incentives to invest in innovation. The Center for Global Development (CGD) and the Market Shaping Accelerator (MSA) are developing an Advance Market Commitment (AMC) to address these market failures and incentivise the development of rapid diagnostics for neonatal sepsis. To support this, we are convening a group of world-leading experts in health, economics and policy, chaired by Lord Jim O'Neill. This builds on the success of the $1.5 billion Pneumococcal Advance Market Commitment which was also incubated at CGD.

The Challenge

Neonatal sepsis is a systemic bloodstream infection occurring within the first 90 days of life and is treatable with antibiotics. It affects 1.3-3.9 million neonates per year and causes 400,000–700,000 deaths per year, primarily in low- and middle-income countries (LMICs). While treatable with antibiotics if identified early, current diagnostic methods—which take 48 to 72 hours—cannot guide crucial and life-saving initial treatment decisions. As a result, clinicians currently rely on their judgment of non-specific signs and symptoms to diagnose neonatal sepsis. This leads to both preventable deaths from missed diagnoses and unnecessary antibiotic use that drives antimicrobial resistance (AMR).

An accurate and rapid point-of-care test would address this global problem by enabling appropriate and timely treatment. The global need for such diagnostic tests is well-established, including by the WHO. Our preliminary analysis, which will be refined further, suggests such a test would be cost-effective.a diagnostic priced at $5, which meets the WHO specifications, could save an additional healthy year of life for $15 where used in community health facilities ($15/DALY). We also estimate it would reduce 60% of unnecessary antibiotic prescriptions for sepsis in neonates.

Rapid diagnostics for neonatal sepsis are likely technologically feasible, based on current R&D pipelines as described by Celik et al 2022 and Tam and Bendel 2017; technologies include: biomarker based approaches, molecular diagnostics, metagenomic techniques, machine learning and AI technologies , as well as other novel approaches.

Despite the clear need and their likely feasibility, investment has been reflecting market, government and institutional failures. These include:

- Inability to price in public health benefits (including undervalued antibiotic stewardship - a public good)
- firms anticipating prices may be driven down by copycat firms or powerful public buyers undermining the incentive to innovate in the first place
- Institutional factors such as regulatory uncertainty, high costs of generating clinical evidence, and fragmented demand signals, which exacerbate risk and delay returns.

Together, these dynamics leave this high-value innovation commercially unattractive despite its huge social value.

The Opportunity

An Advance Market Commitment (AMC) could help tackle these market failures. By promising, in advance, to reward firms that develop and scale up diagnostics that meet the target product profile, it would provide a signal to pioneering firms that they could make attractive returns and recoup their investment costs. It would also create an incentive for innovators with different approaches to take on this problem.

Our current estimates suggest that an AMC on the order of $120 million providing a $5 top-up subsidy for test purchases would motivate firms to invest in diagnostic innovation. The $5 subsidy would be used to match $3 co-payments from health providers. We expect these numbers to change — the current $3 co-payment price was informed by WHO TPP (which sets this as an ideal price-point for this diagnostic test at scale) — as a lower copayment price and more generous subsidy may be required to secure the participation of LMIC health providers. Making an AMC happen requires getting the incentive design right, signing up countries to buy tests, and funders to commit. This calls for a mix of health, economics, and policy expertise. CGD and MSA are therefore convening a working group led by Lord Jim O'Neill, who chaired the UK Government's 'The Review on Antimicrobial Resistance'.

This effort builds on the success of the $1.5 billion Pneumococcal Advance Market Commitment. The AMC was followed by the development of three vaccines tackling strains in low and middle-income countries which saved an estimated 700,000 lives. The Pneumococcal AMC incubated by CGD working group and drew on the expertise of the MSA Faculty Directors Rachel Glennerster, Michael Kremer and Christopher Snyder.

Funding the working group is a high leverage opportunity. It would help mobilize wider funding for an AMC that would incentivize a much needed and cost-effective diagnostic tool

The Path Forward

Our primary objectives for the NeoTest by the end of 2026 are:

- Design an AMC adapted to the specific market failures and incentive problems associated with neonatal sepsis diagnostics
- Secure sufficient funding to make the AMC incentive attractive to private developers
- Support target countries in taking steps that enable them to purchase qualifying tests and signal interest in doing so. We will support countries on providing a credible path through regulatory approval to procurement by health systems to strengthen the demand signal of the AMC. We are currently prioritizing India, South Africa, Tanzania, and Kenya.

Long-term success (2–8 years) will be measured by the accelerated development and deployment of rapid diagnostic tests and resulting reductions in neonatal mortality where they are introduced.

Ways you can get involved

We invite discussions and collaborations with: health ministries and public health agencies interested in being involved in NeoTest and using neonatal sepsis diagnostics; economic, health industry, and policy experts; and funders who are interested in supporting this catalytic initiative.